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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,547	12/12/2003	Rich Ewers	USGINZ02511	2408
40518	7590	11/21/2007		
LEVINE BAGADE HAN LLP 2483 EAST BAYSHORE ROAD, SUITE 100 PALO ALTO, CA 94303			EXAMINER WOO, JULIAN W	
			ART UNIT 3773	PAPER NUMBER
			MAIL DATE 11/21/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/734,547

Applicant(s)

EWERS ET AL.

Examiner

Julian W. Woo

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3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-19 and 32-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-19 and 32-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11/8/04 6/8/05
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of claims 11-19 and the addition of claims 32-41 in the reply filed on September 6, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 11 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Liddicoat et al. (6,702,826). Liddicoat et al. disclose, at least in figures 22-24 and in col. 3, lines 29-55 and col. 8, line 48 to col. 9, line 25; a method of endoscopically forming, approximating and securing a plurality of tissue folds, the method including endoscopically forming a first tissue fold (portion of 3' between 105'); placing a first anchor (106') across the tissue fold; forming at least one additional tissue fold (portion of 3' between 105'), thereby forming the plurality of tissue folds; placing at least one additional anchor (106') across the at least one additional tissue fold; approximating the

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plurality of tissue folds (with 500); and securing the approximated plurality of tissue folds with the anchors, where the first tissue fold and the at least one additional tissue fold are not attached to one another.

4. Claims 11-19, 32-36, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Filipi et al. (5,088,979). Filipi et al. disclose, at least in figures 1a-1d and 4a-4d and in col. 2, line 15 to col. 3, line 18 and col. 3, line 41 to col. 4, line 65; a method of endoscopically forming, approximating and securing a plurality of tissue folds (e.g., 25), the method including endoscopically forming a first tissue fold; placing a first anchor (55) across the tissue fold; forming at least one additional tissue fold, thereby forming the plurality of tissue folds; placing at least one additional anchor (55) across the at least one additional tissue fold; approximating the plurality of tissue folds (i.e., making the folds tighter or tissues closer together with staples 55); and securing the approximated plurality of tissue folds with the anchors, where the first tissue fold and the at least one additional tissue fold are not attached to one another. Filipi et al. also disclose a method of performing gastric reduction procedure including endoscopically forming, approximating and securing a first plurality of tissue folds (e.g., 25, as formed by the plurality of needles 88) in a first plane within a patient's stomach, and endoscopically forming, approximating and securing at least one additional plurality of tissue folds (e.g., diametrically opposite the first plurality of folds) in at least one additional plane within the patient's stomach (where the planes are tangential to the outer surface of the esophagus), where the first plane and the at least one additional plane are substantially parallel to one another, where the first plurality of tissue folds are

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not attached to one another, where the first plurality of tissue folds and the at least one additional plurality of tissue folds each comprise at least one tissue fold from an anterior segment of the patient's stomach and at least one tissue fold from an opposing posterior segment (i.e., stomach segments surrounding the esophagus include anterior and posterior segments), where the first plurality of tissue folds and the at least one additional plurality of tissue folds are disposed inferior to the gastroesophageal junction. Filipi et al. also disclose a method including advancing an overtube (70) through a patient's esophagus into the patient's stomach while the overtube is disposed in a flexible state; transitioning the overtube to a rigid state (with the use of guidewire 5) in a desired orientation within the patient's stomach, and where the distal region of the overtube is located near and inferior to the gastroesophageal junction.

5. Claims 32, 37, 38, and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Matsui et al. (6,352,503). Matsui et al. disclose, at least in figures 23 and 44-47 and in col. 11, line 50 to col. 12, line 5 and col. 17, lines 23-45; a method of performing endoluminal gastric reduction including advancing an overtube (101) through a patient's esophagus into the patient's stomach while the overtube is disposed in a flexible state; transitioning the overtube to a rigid state (at 111) in a desired orientation comprising an arc traversing at least about 180 deg. within the patient's stomach and approximating and securing first and second pluralities of tissue folds in respective first and second planes (at 187), where the method includes advancing a plicaton apparatus (186) through a first lumen in the overtube and a gastroscope (light guide) through a second lumen (at 114) contained in the overtube.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsui et al. (6,352,503) in view of Harrison (5,403,326). Matsui et al. disclose the invention substantially as claimed, but do not disclose that the desired orientation of the overtube comprises an arc traversing approximately 270 deg. Harrison teaches, at least in figure 8A, an overtube (58) having an orientation comprising an arc traversing approximately 270 deg. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Harrison, to modify the overtube of Matsui et al., so that it can be oriented as claimed. Such an orientation would allow the overtube to access and visualize tissues in difficult-to-reach locations for the formation of tissue folds.

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***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo  
Primary Examiner

November 18, 2007